AUG - 7 2001

K011695

510 (k) Summary of Safety And Effectiveness

Applicant name and address:	Collagen Matrix, Inc. 509 Commerce Street Franklin Lakes, NJ 07417
Contact person and telephone number:	Shu-Tung Li, Ph.D. President & CEO Tel: (201) 405-1477
Date of summary:	May 24, 2001
Device generic name:	Collagen Dental Membrane
Device trade name:	None
Predicate device:	BioGide®, [510(k) #K960724]

Description of the device:

The Collagen Dental Membrane is a resorbable, type I collagen matrix of defined geometry, *in vivo* stability, permeability and mechanical strength for use as a material to aid in wound healing in bone repair, ridge augmentation and dental implant procedures.

The device is provided in two sizes 20 mm x 30 mm and 30 mm x 40 mm. The device can be easily trimmed for a final fit during surgery to the appropriate size and shape required for the defect to be treated.

Intended Use of the Device

Collagen Dental Membrane is intended for use in oral surgical procedures as a resorbable material for placement in the area of dental implant, bone defect or ridge augmentation to aid in wound healing post surgery.

Technical Characteristics

Collagen Dental Membrane has been designed in accordance with the accepted principles of guided bone regeneration (GBR) as a wound healing material post surgery.

Specifically, the device is designed to be resorbable, biocompatible, cell occlusive, clinically manageable, and suturable.

Summary of Biocompatibility Studies

The Collagen Dental Membrane is biocompatible based on the tests recommended by the FDA.

Summary of *In Vivo* Resorption Studies

In vivo resorption time for the Collagen Dental Membrane was evaluated in a rat subcutaneous implantation model. The results of the studies showed that Collagen Dental Membrane has an *in vivo* resorption time from 26 to 38 weeks.

Summary of Effectiveness Data

Animal Data

The concept of "Guided Bone Regeneration (GBR)" in bone repair, ridge augmentation and dental implant surgeries has been proven from animal model studies. That is, during the surgery, a barrier membrane is placed over the bone, ridge or dental implant to retard and/or prevent the down growth of epithelium, and to prevent the contact of gingival connective tissue with the implant and bony surface. Thereby, bone cells can grow into the defect site to fill the defect space or integrate with the dental implant for a firm anchor of the implant within the bone socket.

A comprehensive literature search showed that numerous materials have been studied as a barrier in the GBR studies in various animal models. The animal data provided evidence that the concept of GBR using membranes as a barrier to aid in wound healing has been verified using either resorbable or non-resorbable membranes is a valid approach.

b. Summary of Clinical Data

Results from human studies from the literature are consistent with animal studies. Similar to animal studies, the materials studied thus far, resorbable and nonresorbable,

are both effective as a barrier to aid in wound healing in dental implant, ridge augmentation and bone repair procedures.

Conclusion

Thus, based on the biocompatibility testing conducted on the Collagen Dental Membrane and literature research on the various membranes, we conclude that the Collagen Dental Membrane is safe for implantation and is effective as a resorbable membrane to aid in wound healing post dental implant, bone repair and ridge augmentation surgeries. The Collagen Dental Membrane is substantially equivalent to BioGide®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2001

Mr. Shu-Tung Li
President
Collagen Matrix, Incorporated
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K011695
Trade/Device Name: Collagen Dental Membrane
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LYC
Dated: May 30, 2001
Received: May 31, 2001

Dear Mr. Li:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011695

Device Name: Collagen Dental Membrane

Indications for Use:

Collagen Dental Membrane is intended for use in oral surgical procedures as a resorbable material for placement in the area of dental implant, bone defect or ridge augmentation to aid in wound healing post surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Donald W Shupp for MSR

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K011695